

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/976,468	DIMARTINO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Patrick T. Lewis	1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment dated August 3, 2005.
2. ☒ The allowed claim(s) is/are 45-47, 49-54 and 56-86.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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|---|--|
| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date <u>08232005; 08052005</u></li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>10042005</u>.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
|---|--|

  
 Patrick Lewis, PhD  
 Examiner  
 Art Unit 1623

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Shirley Chen on October 4, 2005.

The application has been amended as follows:

In claim 45, line 1, the phrase "preventing or" has been deleted; in line 6, the phrase "or about 0.05-5 mg/m<sup>2</sup>" has been deleted.

In claim 53, line 2, the range "0.1-2" has been deleted and the number ---2--- has been inserted therefor.

In claim 54, line 2, the range "0.5-1" has been deleted and the number ---1--- has been inserted therefor.

In claim 58, line 4, after the term "amount", the phrase ---of about 1-10 mg/m<sup>2</sup>--- has been added.

In claim 67, line 2, the range "0.1-2" has been deleted and the number ---2--- has been inserted therefor.

In claim 68, line 2, the range "0.5-1" has been deleted and the number ---1--- has been inserted therefor.

In claim 71, line 2, the range "0.5-1.5" has been deleted and the number ---1.5--- has been inserted therefor.

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In claim 73, line 2, the range "0.5-1.5" has been deleted and the number ---1.5--- has been inserted therefor.

In claim 75, line 2, the range "0.5-1.5" has been deleted and the number ---1.5--- has been inserted therefor.

In claim 77, line 2, the range "0.5-1.5" has been deleted and the number ---1.5--- has been inserted therefor.

In claim 83, line 2, the range "0.5-1.5" has been deleted and the number ---1.5--- has been inserted therefor.

In claim 86, line 2, the range "0.5-1.5" has been deleted and the number ---1.5--- has been inserted therefor.

### ***Reasons for Allowance***

2. The following is an examiner's statement of reasons for allowance:

Waller US 5,800,539 is closest related prior art. Waller teaches a method of transplanting hematopoietic system reconstituting cells from a donor source into an allogeneic recipient comprising administering to the recipient, prior to the administration of the hematopoietic system reconstituting cells, an amount of mononuclear cells which are treat so as to render them incapable of proliferating and causing a lethal GVHD effect. The mononuclear cells are treated with cytotoxic chemotherapeutic drugs to render the cells incapable of proliferating and causing GVHD. The treated mononuclear cells are administered to the recipient at any time prior to the administration of the hematopoietic system

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reconstituting cells. Any range of treatment, e.g., one to nine, two to eight, three to seven, one to two, one to three, zero to one, zero to two days, etc. are also provided. However, the prior art does not teach or suggest administering pentostatin to the transplant recipient directly to prevent or reduce the risk of developing GVHD.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Patrick T. Lewis, PhD  
Examiner  
Art Unit 1623

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